REPLY DECLARATION OF CHRISTOPHER J. MCDONALD IN FURTHER SUPPORT OF END-PAYOR PLAINTIFFS' MOTION FOR CLASS CERTIFICATION [PUBLIC VERSION]

Exhibit 65

Part 2 of 3

PHARMACY BENEFIT MANAGEMENT COMPANIES (PBMs)[27]

Pharmacy benefit management companies, or pharmacy benefit managers, abbreviated as "PBMs," are specialized business entities established to provide a broad spectrum of outsourced pharmacy benefit management services for their private and public payer-customers on a stand-alone or carve-out basis. That is, the management of the pharmacy benefit is "carved-out" from internal management within the health plan and provided by an external PBM. Carve-out services are not unique to pharmacy. It has been very common for HMOs to carve out mental health, dental, and chiropractic services to external management companies. The basic business reasons for an employer group, an MCO, or an insurer to use a PBM are the potential for lower developmental and operational program costs, reduced development time, breadth of flexible data processing services, and other clinical and patient care services provided by the PBM. Certainly an HMO can internally develop the capabilities offered by a PBM. There may be reasons of cost-efficiency to justify using an external PBM rather than building internal pharmacy benefit program capabilities. This is an important concept: If the internally developed pharmacy benefit management program does not offer competitive cost or quality advantages, it may be a wise business decision for the MCO to "buy" PBM services rather than "build" them internally. PBMs exist and thrive because they are highly cost-efficient and flexible in providing customized pharmacy program management because of their specialized pharmacy benefit resources and economies of scale.

Genesis of PBMs

PBMs generally developed as separate, independent companies or from within HMOs. The earliest third-party prescription drug management programs, Prescription Card Services (PCS) and Medco Containment Services, came into existence in the 1970s to provide third-party prescription drug programs primarily for self-insured companies. The second route of PBM development, from within HMOs, occurred as a natural evolution from successfully managed internal HMO pharmacy programs. These HMOs saw an opportunity to commercialize their successful strategies and offer pharmacy management services to external customers without adequate internal resources. In 1987, Diversified Pharmaceutical Services (DPS) was one of the earliest examples of a PBM that grew from within an HMO (United HealthCare [UHC]).

These three early PBMs—PCS, Medco, and DPS—were born from three different heritages and displayed unique benefit management philosophies. PCS developed to offer third-party prescription care benefits primarily to employer groups using a vast network of community chain and independent pharmacies. Medco Containment Services developed for similar reasons but focused on mail service to dispense and distribute prescriptions. DPS developed from the pharmacy department within an HMO and had primarily a clinical focus to its pharmacy benefit management strategies. Therefore, the three early PBMs grew from very diverse origins but eventually evolved to become more similar than dissimilar realizing that they must take advantage of the efficiencies of all types of pharmacy benefit management and distribution strategies to successfully meet the needs of their diverse and evolving customer base. As a result, these three, and other PBMs, became similar in the products and services they offered employer group and HMO customers. However, not all PBMs enjoyed the same performance success.

Soon after the success of United HealthCare's PBM subsidiary DPS, other HMOs with internal pharmacy departments began to offer their programs to noncompeting HMOs, self-insured employers, and government-funded programs, such as the state Medicaid programs. Examples of some of the PBMs that developed as internal HMO pharmacy program management are found in Table 15–1. By the late 1980s, the term "pharmacy benefit management company" or "pharmacy benefit manager" or "PBM" became popular, although its exact origin is unknown.

Table 15–1 Examples of PBMs Originally Developed from within HMOs

Parent HMO	*PBM*
United HealthCare	Diversified Pharmaceutical Services
Blue Cross Blue Shield of Minnesota	Pharmacy Gold
Blue Cross of California	WellPoint Pharmacy Management
Blue Cross Blue Shield of Maryland	Advance Paradigm
General American (Sanus; NY Life)	Express Scripts
PacifiCare Health Systems	Prescription Solutions

PBMs have continued to grow in number and in membership. Table 15–2 displays the larger PBMs and their membership. Although some double-counting may exist (e.g., members obtaining mail order or Internet pharmacy services from one PBM and retain pharmacy services from another), the PBM membership is estimated to be 246 million, or more than 80 percent of the entire U.S. population. The PBM market is dominated by a small number of large companies. According to the reported membership in PBM corporate websites, the combined membership of the six largest PBMs is 219 million or more than 90 percent of all estimated PBM lives.

There has also been much ownership change and consolidation within the PBM industry. For example, PCS Health Systems, Inc. (the PBM's current name), originally an independent company, was purchased by McKesson Drug (a drug wholesaler), then Eli Lilly & Company (a pharmaceutical manufacturer). Rite Aid chain pharmacy company finally purchased it in 1999, and PCS is reportedly again for sale as of the end of 1999. Another example of ownership change occurred with DPS. The PBM developed within the UHC pharmacy department and began offering pharmacy management services to non-UHC health plans in 1987. The drug manufacturer SmithKline Beecham purchased DPS in 1994, and it was subsequently purchased by Express Scripts, Inc., an independent PBM, in 1999. It is interesting to note that PCS and DPS were last sold for approximately one third of their original purchase price.

Table 15–2 Largest PBMs, Ownership Status, and Membership

PBM Company	*Membership (millions)*
Merck-Merck Managed Care	51
PCS Health Systems	>50
Express Scripts	47
Advance Paradigm	27
MedImpact	26
WellPoint Pharmacy Management	18
Others (est.)	27
Total	246 million lives

Source: Data from PBM websites, January 2000.

Rationale for Using a PBM

The decision for an MCO to develop and operate an internal pharmacy program or to contract with an external PBM depends on many factors. Essentially, the MCO must determine whether it can "build" and efficiently operate an internal infrastructure to manage prescription drug benefits or whether it is more efficient to "buy" this service from an external PBM company. In fact, many MCOs will build certain internal management capabilities and buy other operational "commodity" services, such as claims processing, from a PBM.

A PBM offers certain advantages in the build versus buy evaluation. The primary advantages of using a PBM to provide pharmacy services are the MCO can save the program development costs, eliminate a significant information system investment, implement the program in a much

shorter time frame, and minimize operational expenses. Building and maintaining internal pharmacy management services are expensive and time consuming exercises that require ongoing operational support to maintain system components and provide continuous upgrades.

The services of a PBM can be implemented rapidly. The pharmacy networks, information systems, manufacturer contracts, and other standard program components already exist and can be rapidly implemented flexibly to meet customer-specific requirements. Large MCO customers with multiple products and complex benefit designs may require significant customization, and a PBM may be able to better provide such diverse services because of information system capabilities.

Hybrid Pharmacy Program Management Using PBMs

Even though an MCO has the option of building or buying pharmacy management services, it often decides to take advantage of both options through a hybrid program. Thus, it is quite common for an HMO to build an internal pharmacy *management* program and also use a PBM for specific, basic resource-intensive *operational* services that take advantage of a PBM's economies of scale. The program components that should be built or at least managed internally are those that the MCO or employer group believes it can do in a cost-efficient manner that will provide a long-term, differentiating, competitive advantage. Even though a PBM has the ability to offer a turnkey pharmacy benefit management program and the *à la carte* components, it is important for a PBM customer to be actively involved in design of the benefit and oversight of the program performance to ensure objectives are achieved. Table 15–3 lists the PBM services commonly used by 70 HMOs.[28] These findings demonstrate that HMOs contract with PBMs for core commodity services, especially claims processing, but HMOs often maintain internal control of clinical programs that may provide competitive differentiation.

Table 15–3 PBM Services Used by HMOs

PBM Service	Percent of HMOs Obtaining This Service from a PBM
Claims processing	86%
POS edits	76%
DUR programs	54%
Pharmacy network development and management	50%
Formulary management	46%
Physician intervention	34%
Demand management	22%
Disease management programs	16%
Treatment guidelines	15%
Outcomes management	6%

Source: Reprinted with permission from RP Navarro (ed), *Pharmacy Benefit Report Trends & Forecasts*, Issue 21, © 1998, Novartis Pharmaceuticals Corporation.

Reintegrating the Value of PBM Services

PBMs are successful in providing stand-alone pharmacy benefit management because of their singular focus, dedicated resources, experience, and economies of scale. However, although carving out the pharmacy benefit for efficient management may achieve pharmacy program cost-containment objectives, this component, or silo management, may cause payers to focus on pharmacy program cost rather than value. As discussed earlier, appropriately used pharmaceuticals provide tremendous clinical and economic value. It is critical that the positive impact the pharmacy benefit can have on other direct medical costs and quality of life are not lost. Therefore, PBMs and their clients are attempting to integrate prescription claims data with medical claims and clinical data so that the interrelationship of the various health care delivery components can be recognized. MCOs, employer groups, and other customers "carve-out" the pharmacy benefit to a PBM for management and

"carve-in" the pharmacy outcomes data into their overall health care delivery management process so that the overall value of pharmacy is recognized. This ensures that pharmacy benefit management decisions are consistent with the overall health care delivery process and not made in isolation. Although component cost will always be important, the reintegration of pharmacy data in overall health care management will help promote drug benefit designs that balance cost and quality of care objectives. This value reintegration philosophy is supported by all stakeholders in the pharmacy benefit management continuum, including pharmaceutical manufacturers, pharmacists, PBMs, and their customers. The primary challenge to achieving this value reintegration goal has been the inadequacies of managed care information systems to capture, merge, and report accurate and complete integrated outcomes data.

In summary, a PBM may offer cost-efficient outsourcing of some or all pharmacy program management components. The HMO or self-insured employer group must consider the advantages of using a PBM and determine what components can be carved out and what should be maintained within the health plan to maximize the efficiencies and resources of each entity.

PHARMACY BENEFIT MANAGEMENT PROGRAM COMPONENTS

Pharmacy benefit management strategies have changed very little in concept over the past 20 years. However, the growth and acceptance of managed care and the expansion of information technology have increased the success with which these concepts can be executed. The success with which they are implemented can also vary greatly among the various MCOs, depending on the aggressiveness of their employer groups and the resources and expertise of the MCO or PBM. Most managed care prescription drug benefits include the following basic components:[29]

- legally enforceable benefit design contract outlining covered benefits
- defined physician provider network under contract with the health plan
- defined pharmacy provider network under contract with the health plan or PBM required to use a POS prescription adjudication system
- enforceable drug formulary
- mandatory generic substitution program
- pharmaceutical manufacturer discounts or rebates
- patient prescription copayment
- retrospective drug utilization review (DUR)

Advanced programs may include additional components, such as drug conversion or switching programs, compliance interventions, and disease management programs.

Pharmacy Benefit Design

The first step in developing a pharmacy benefit is to ensure that a legal contract exists between the parties (i.e., employer group and HMO, HMO and PBM, employer group and PBM). The contract must be filed with the individual state regulatory agency and may be called a Certificate of Coverage, Evidence of Coverage, Certificate of Benefits, or other similar name. It is a legally enforceable contract by which the MCO (i.e., HMO or PBM) agrees to provide explicitly defined prescription drug benefits for a specific price and the purchaser of the benefit (payer) agrees to accept the defined covered benefits according to certain coverage and access rules.

The Certificate of Coverage is a legal document filed with state regulatory agencies that explicitly states the following:[30]

- what persons are eligible for benefits (e.g., employer group employees and their dependents)
- what benefits are covered (e.g., legend drugs requiring a prescription by a physician)
- what benefits are not covered (e.g., nonprescription drugs, injectable drugs, experimental drugs)

- what benefit limitations exist (e.g., prescriptions for up to a 30-day supply through a retail pharmacy and up to a 90-day supply through mail service)
- additional requirements for coverage (e.g., drugs must be included on the health plan's or PBM's formulary)
- how benefits are accessed (e.g., members must obtain a prescription from a plan physician and must have the prescription filled at a plan pharmacy)

A Certificate of Coverage may include other policies and procedures, but the elements listed previously are the most standard types of information included. A member should be able to clearly understand the extent and limits of the benefits by reading the Certificate of Coverage. This document often includes the procedure for resolution of a grievance or for the member to obtain coverage for a nonformulary drug. The Certificate may not be changed without the approval of both signatory parties (e.g., MCO and employer group) and usually changes only at annual contract renewal, although a mid-year contract addendum may be used to change mutually agreeable terms.

Legal Basis of Pharmacy Benefit Management

John Jones of PacifiCare lists the following factors that allow the organization to exercise pharmacy benefit controls:[31]

- Boards of pharmacy in each state regulate pharmacy, individual state agencies regulating controlled substances, the United States Food and Drug Administration, and the United States Drug Enforcement Agency.
- Many states have established regulations governing the operation and administration of HMOs. Most involve enforcement by a regulatory agency such as the state Department of Insurance, Department of Corporations, or Department of Health Services.
- A body of federal law governing the provision of health benefits is the Employee Retirement Income Security Act of 1974 and the rules and regulations passed into law subsequently. They are collectively known as the ERISA laws. Employer groups, pharmacy benefit management companies, and HMOs are generally protected by federal ERISA laws from liability for their administration of pharmacy benefits designed or selected by the payers for their covered members (although some states are challenging this liability exemption with state legislation).
- PBMs do not prescribe medications or practice medicine; they administer prescription drug benefits according to parameters established by the employer or health plan and according to the physician's prescription.
- Formularies are lists of drugs selected by a pharmacy and therapeutics (P & T) committee through a deliberative process and are administered according to the benefit design by the PBM. Plan members are not prohibited from receiving prescriptions for nonformulary drugs, but the plan is not generally bound to pay for nonformulary drugs unless the plan is bound to cover all medically necessary drugs. Medical necessity is generally determined by the plan according to specific criteria established by the P & T committee or by a pharmacist or physician by means of a prior authorization process or by review during an appeal.
- Beneficiaries are notified that their prescription drug benefits are limited. This notification is generally done through an explanation of benefits (EOB) document that members receive from their health plan or employer. When they file a claim for prescription coverage, the EOB must clearly state which drugs are covered and which are excluded, either naming the drugs individually or by treatment category.
- Some states and occasionally the federal government have established mandatory coverage of certain drug treatment categories that must be included if a pharmacy benefit is offered.
- PBMs contract with pharmacies to provide services to members. The contractual obli-

gations must satisfy state licensure and record keeping requirements.

Some states have strong regulatory agencies that enforce laws created to govern the activities of health plans and protect the consumers. Health plans and the PBMs with which they contract must comply with the laws of those states. Generally, the health plans must provide medically necessary treatment within the guidelines of the health plan benefit policy

PHYSICIAN PROVIDER NETWORK

The health plan may employ physicians, or more likely it will contract with community physicians and medical groups. Community physicians that are under contract with a health plan are often referred to as "participating providers." Health plans employ or contract with physicians to obtain a discounted reimbursement in exchange for allowing the physician to care for the health plan's patients (members). Although a physician provider network is generally not considered part of the pharmacy benefit program, the health plan must include physicians in the pharmacy benefit design because they prescribe the drugs that are to be covered.

Contracts with participating physician providers usually state that they will prescribe drugs in accordance with the plan's drug formulary and other pharmacy benefit policies. If a physician or medical group accepts financial risk for the cost of pharmacy benefits, the physician provider contract will outline this risk-sharing arrangement (see Chapter 7). The contract also details periodic drug prescribing drug utilization review "report cards" that physicians can expect to receive periodically that allow them to compare their prescribing habits and drug costs with other physicians in their specialty peer group. As stated previously, more HMOs are sharing the financial risk of the pharmacy benefit with participating physicians in an attempt to sensitize prescribers to the cost of drugs. This practice is more common on the West Coast and in the Northeast but is increasing in many states. Regrettably, physicians often do not know the details of their pharmacy risk contract, and they frequently lose money on these relationships.

PHARMACY PROVIDER NETWORK

How the member obtains the final prescription product is an important link in the pharmacy benefit process. The MCO or PBM will own or contract with community pharmacy providers, Internet pharmacies, or mail service pharmacies to control both the drug ingredient cost and administrative costs (dispensing fee, packaging, distribution fees, claims adjudication fees, etc.). The MCO will also require the contracted pharmacy distributor to dispense drugs in conformance with the drug formulary to maximize the MCO's discount or rebate contracts with pharmaceutical manufacturers. The health plan must define its prescription distribution channels so that drug costs and dispensing process costs can be controlled effectively. There are three primary channels to distribute pharmaceuticals:

- owned, in-house pharmacies within health plan medical centers (usually staff and group model HMOs)
- independent and chain community retail pharmacies
- mail service pharmacies and Internet pharmacies

Owned, in-house pharmacies and community-based retail pharmacies dispensed more than 85 percent of outpatient prescriptions. Mail order prescription volume has remained relatively constant at about 12 percent of the total retail prescriptions, but its volume is growing by about the same annual percent.

Internet Pharmacies

Internet pharmacies are becoming increasingly popular. In reality, Internet pharmacies may be considered a high-tech mail service pharmacy because they distribute prescriptions by mail or overnight package delivery service. However, they allow access to prescription ordering and refills through the Internet in addition to the telephone or

fax (common with all mail service pharmacies). Although the dispensing "back end" of Internet pharmacies may be no different than mail order pharmacies, the "front end" patient health and drug information services and patient access are quite novel. Some traditional mail service and chain pharmacies now offer Internet access for patients to order refills, non-prescription drugs, or health and beauty products similar to Internet pharmacies. Examples of Internet pharmacies as of 2000 include HealthCentralRx.com, PlanetRx.com, YourPharmacy.com, DrugStore.com, and many others. In December 1999, a national concern regarding the lack of adequate regulations governing the operation of Internet pharmacies may result in the FDA licensing or certifying Internet pharmacies. These concerns are largely due to some Internet pharmacies that will mail prescription drugs without a prescription or will offer an "online consultation" with a physician (or someone claiming to be a physician) that will result in a "prescription" being written. Some Internet pharmacies, possibly operating outside of the United States, will distribute unapproved or experimental drugs within the United States.

Internet access to prescription drugs is an extension of the "e-tailing" phenomenon, whereby individuals are becoming increasingly comfortable with Internet shopping. In addition to allowing an interesting and interactive method of communicating, the Internet pharmacies provide a broad array of patient health information, drug education, hot links to other health-related websites, and access to a wide variety of discounted health and beauty products that can be sent by overnight mail. Many pharmacy chains and PBMs have developed their own Internet portals to their pharmacy services, and many have established partnerships with other Internet pharmacies. For example, Express Scripts has announced it has selected PlanetRx as its exclusive Internet pharmacies. The power of the Internet can provide definite patient care advantages, such as access to targeted and comprehensive health and drug information, as well as offering automated refill monitoring to support patient compliance and persistence programs.

Specialized Distribution Networks

A specialized network is developed to accommodate a specific class or type of drug (e.g., interferon, AIDS therapy, injectables) or services available (e.g., anticoagulation clinics or home infusion); such services are frequently associated with disease management programs (see Chapter 14). The services may thus require specialized education in a particular disease state, patient monitoring, or concentrated consultations. It may require the willingness to maintain an inventory of specialized medications or injectables. Credentialing and/or certification may be required to ensure quality and consistency when delivering professional services. Reimbursement can be based on both the product cost and the amount of time necessary to deliver the service.

Prescription distribution channels are not mutually exclusive, and MCOs often use two or more channels. For example, an IPA or network model HMO will contract with community pharmacies to form a pharmacy provider network and may also contract with a mail service pharmacy. A staff or group model health plan may have owned pharmacies within its medical centers in a metropolitan area and augment the owned pharmacies with a community pharmacy network and a mail service pharmacy. Chain pharmacies in the MCOs community network may also provide mail service prescriptions and allow Internet access, as discussed previously.

Physician Dispensing

Some health plans may reimburse physicians for dispensing drugs directly from their office, but this is an uncommon practice and most often occurs only in rural areas without adequate coverage of community pharmacies. In general, health plans will not reimburse physicians for dispensing drugs unless the physician's office agrees to accept the same level of reimbursement as is paid to pharmacies and if the physician's office submits pharmacy claims through a POS terminal. Physician dispensing units often contain a limited amount of acute-

care drugs and generally promote the use of generics. Some applications link in-office physician dispensing units for acute care drugs with mail order for chronic care medications.

Retail Community Pharmacy Network

There are currently 50,000 community retail pharmacies (30,000 chain and 20,000 independent). Chain pharmacies dispense 60 percent of all outpatient prescriptions, about 1.6 billion per year, or 400 million per day.[32] The food stores with pharmacies represent the fastest growing retail pharmacy segment, with a 13.8 percent growth in prescription volume from 1997 to 1998. During the same period, chain pharmacy prescription volume increased 8.8 percent, and independent prescription volume increased 1.2 percent.[33]

Health plans and PBMs often contract with a broad network of retail and chain community pharmacies to ensure members have easy access to pharmacy benefits. In an area without significant managed care penetration, MCOs or PBMs may find it necessary to barter members for discounts. That is, pharmacies may be unwilling to accept discounts on prescriptions unless they are members of a relatively exclusive pharmacy provider network and believe they will have access to members because of their participation. Conversely, if they elect not to accept the discounts and not to participate in the provider network, managed care members will likely not patronize their pharmacies because their prescriptions would not be covered at the nonparticipating pharmacies. Therefore, the MCO or PBM will offer their contracted members to the pharmacies if they agree to accept discounted reimbursement and participate in the network.

When constructing a pharmacy provider network, it is relatively easy to construct a network around chain pharmacies. Generally, they are very willing to accept discounts to lure managed care customers into their stores. In fact, in most metropolitan areas, it is likely that an adequate pharmacy provider network can be constructed of 80 percent chain pharmacies and 20 percent independent pharmacies. However, for competitive purposes, many large MCOs offer a variety of access points for prescriptions through a hybrid distribution network that is focused around community pharmacies but also includes mail service pharmacies or chain pharmacies, both of which may be accessed by way of the Internet. Staff or group model HMOs may also have some in-house pharmacies in owned medical centers.

Pharmacy Provider Contract

All participating pharmacies are bound by a contract (provider agreement) that stipulates that the MCO or PBM will reimburse the pharmacy for approved prescriptions dispensed to their members in accordance with drug benefit and coverage policies. The pharmacy agrees to accept a discounted level of reimbursement and to follow the defined dispensing policies and procedures. These policies are usually detailed in a policy and procedure manual provided to each pharmacy and updated from time to time by the MCO or PBM. A pharmacy provider contract will generally include the following requirements:[34]

- The health plan or PBM agrees to allow their members to obtain prescriptions from the contracted pharmacy only. (Some states with any willing provider laws will allow noncontracted pharmacies to be reimbursed at the contract rate of the dispensed prescriptions to managed care members; see also Chapter 35 for a discussion of state any willing provider laws.)
- The health plan or PBM agrees to pay the pharmacy within a specific period (usually every two weeks or less) for all prescriptions dispensed according to a contracted reimbursement schedule.
- The pharmacy agrees to accept a defined reimbursement for each prescription filled under contract. For example, the contract may stipulate a reimbursement of a 15 percent discount off the AWP for brand-name drugs and 50 percent off the AWP for generic drugs.

- The pharmacy agrees to accept a discounted dispensing fee (e.g., $2.50) for each prescription filled. Typically, up to a 30-day supply is allowed through community pharmacies.
- The pharmacy agrees to accept the patient copayment and health plan or PBM reimbursement as payment in full for the prescription. That is, the pharmacy cannot request that the patient pay more than their copayment (called "balance billing"; see Chapter 32 for discussion of this clause).
- The pharmacy agrees to dispense prescriptions according to the drug formulary and the dispensing requirements specified in the policy and procedure manual.
- The pharmacy agrees to use the in-pharmacy POS computer adjudication system to process and bill all health plan or PBM prescriptions. Use of the system benefits both parties. The pharmacy obtains complete coverage and reimbursement information from the system, and, if the prescription data are accepted by the computer, the pharmacy is guaranteed payment within a specific time frame.
- The pharmacy agrees to participate and dispense prescriptions in conformance with the following additional administrative requirements regarding the dispensing process, according to Sterler and Stevens:[35]
  - —services and standards such as licensing, certification, and continuing education
  - —prior authorization policies that may require the pharmacy to contact the physician in specified circumstances
  - —documentation, including the signature log that documents that counseling was performed and the patient or other authorized person accepted the prescription
  - —record retention requirements beyond those set by state pharmacy or other laws
  - —electronic communication standards requiring transmission and display of all online messages from the claims processor (such as drug formulary compliance, drug interactions, patient eligibility, DUR, DUE) and that appropriate action is taken
  - —pharmacy provider insurance standards
  - —expectations for online and real-time claim submission in the required format
  - —requirements for participation in national pharmacy provider networks
  - —taxes that must be collected
  - —reimbursement policies and accompanying payment reports
  - —enrollment fees the pharmacy must pay to participate in a network
  - —audit and inspection rights of the contractor and responsibilities of the pharmacy
  - —definition of the pharmacy provider records that must be maintained
  - —advertising and trademarks privileges of the contractor

Participating Pharmacy Policy and Procedure Manual

The provider policy and procedure manual details the specific policies and procedures the participating pharmacies must follow to be in compliance with the provider agreement. According to Sterler and Stephens of PCS Health Systems, the manual must be consistent with the performance criteria outlined in the provider agreement. Typical topics addressed in the manual include the following:[36]

- systems requirements (hardware and software requirements of the POS system [current and future upgrades] and data transmission standards)
- drug formulary dispensing policy
- DUR messages transmitted on the electronic system
- enhancements to electronic messages
- incentive programs associated with dispensing performance requirements
- contract compliance and audits
- operational procedures (e.g., signature log and dispense-as-written [DAW] codes)
- components of performance evaluation

PHARMACY PROVIDER AUDITS

Some degree of fraud and abuse is always present within a large pharmacy provider network but can be minimized with a well-designed and thorough auditing system and an effective provider and member educational program. Fraud and abuse can arise from actions of a member, pharmacy, or prescriber and are usually unintentional and simply caused by a lack of appropriate education about a certain procedure. The first line of defense is online claims adjudication using automated real-time POS edits to ensure compliance with program coverage and dispensing policies.

The second line of defense is the audit, with two common types.[37] The first is usually the "bench" or desk audit that analyzes reports on the basis of utilization and cost data to identify erroneous billings and confirm that billed drugs were, in fact, dispensed. A more controversial form of desk audit uses pre-established algorithms to indicate the highest boundaries within which a pharmacy's claims may fall. For all claims that fall outside these boundaries, the pharmacy is held responsible for the dollar amount of these claims. This method is referred to as extrapolation. Because the monetary impact is only detected through exception reports, as opposed to an actual review of the claim, this auditing method is more frequently challenged.

The more common audit is the actual field or on-site pharmacy audit. An auditor personally visits the pharmacy and reviews claims, signature logs, and other substantive documentation within the pharmacy. Pharmacies are targeted for a field audit if the claims analysis indicates a potential problem. Possible actions include on-site inspection of pharmacy documentation, a contact with the prescriber-of-record for validation, or a contact with the patient for validation of receipt of the drugs.

Another form of the field audit is an educational audit. Auditors will answer questions about claims processing, inform pharmacists about programs and policies, and relay pharmacists' concerns back to the processor. Educational material is reviewed to help the pharmacy prevent future problems. Following are some common criteria used to screen pharmacies for potential problems:[38]

- usual and customary (U & C) price submission
- claim submission exceeding a specified number of claims per patient per day
- average ingredient cost paid
- average amount paid per prescription filled
- percentage of compounded claims
- percentage of controlled drugs
- percentage of brand name claims for multisource drugs
- DAW classification
- percentage of refilled prescriptions
- percentage of DAW prescriptions

The pharmacy contract also allows the MCO or PBM to audit the pharmacies in-store records based on possible dispensing or billing irregularities discovered through automated audits of billing records. Pharmacies found to be in violation of the terms of the contract may be terminated from the pharmacy provider network.

DRUG FORMULARY MANAGEMENT[39]

A drug formulary is a preferred list of medications developed by the health plan or PBM to guide physician prescribing and pharmacy dispensing. Formularies are not novel but have been used for decades by hospitals, health plans, and other health care institutions as a method of inventory control and to promote the use of the most cost-effective products.[40] Early formularies in the United States were primarily compilations of formulas and recipes used to prepare medicines. The first hospital formulary, the Lititz Pharmacopoeia (1778), attempted to standardize compounding and dispensing of medicines in military hospitals that were set up during the Revolutionary War.[41] The first civilian hospital formulary, the Pharmacopoeia of the New York Hospital (1816), was the first attempt to incorporate the opinions of the hospital's medical staff in the development of an institutional formulary.[42]

The hospital formulary system, more commonly in place today, had its origins in the 1920s. In 1925, 45 physicians and a pharmacist at Syracuse University Hospital established a scientific basis for drug control and reduction of therapeutic duplications through its drug therapy program. The New York Hospital completed a similar project in 1932.[43]

In the 1960s, the formulary system was established in virtually every hospital in the United States. The publication of the American Hospital Formulary Service (AHFS) in 1959 expanded the use of formularies. The flexibility of the AHFS allowed even the smallest hospital to incorporate a formulary system into its operating policies. Today, the AHFS is a critical component in the formulary system and drug information service of most hospitals and MCO pharmacy departments.

Simply defined, a drug formulary is a list of drugs approved for use within a health care setting. A formulary system is the method and processes used that continually update the formulary's content of prescription medications. The formulary system "...provides for the procuring, prescribing, dispensing, and administering of drugs...."[44] It is a uniquely dynamic system that represents the current body of pharmaceutical knowledge and medical community practice standards resident in the health care setting it serves. Formularies are continuously evaluated by a committee of experts, primarily composed of physicians and pharmacists, working within the health care setting. This committee is most often called the Pharmacy and Therapeutics Committee, or the P & T committee. "The P & T Committee is responsible for developing, managing, updating, and administering the formulary."[45]

The drug formulary is often printed in booklet form and distributed to participating physicians. It is occasionally sent to patients in an abridged form. Drugs that are eligible for coverage and included in the formulary are usually listed by therapeutic category. Additional information included for the prescriber and dispenser include: if the generic and/or brand name form are covered, coverage restrictions, relative cost index (a guide to relative pricing of drugs within the category), and possibly the copayment tier. The copayment tier and especially copayment dollar amount may not be included because of the benefit design differences among the various payer groups that may all seek care from the same provider physicians and pharmacies. Some formularies may include clinical information (e.g., dosing considerations, adverse effects, interactions, age-related dose guidance) and drug use guidelines (e.g., step-care protocols). An example page of a simple drug formulary is found in Exhibit 15–1 (*Note*: copayment dollar amounts are included for illustrative purposes only).

Drug Formulary Selection and Decision-Making Process

The physicians who sit on the P & T committee often represent a wide scope of medical practice by including both primary care physicians and a variety of medical specialties. Other health care professionals, such as nurses, may also be appointed to the committee. Although medicine and pharmacy compose the core of the P & T committee membership, some managed care plans have added additional representatives from a variety of interests, including administration, legal, marketing, or even lay health plan members.

The primary purposes of the P & T committee are to determine drug coverage policy development and enforcement and education to promote safe, effective, and cost-effective pharmaceuticals.[46] Policies are established concerning the evaluation and selection of drugs to be included in the formulary and policies regarding drug utilization review and evaluation. These range from policies regarding relationships with the pharmaceutical industry, drug formulary exceptions, and participation in clinical research.

The P & T committee must meet regularly (usually quarterly with interim conference calls as necessary) to continually revise and update to ensure it is a dynamic reference. P & T committees must consider a number of key points when evaluating a new pharmaceutical to determine whether it should be awarded a position in the

Exhibit 15–1 Example of a Drug Formulary Page

5.0 Antidepressant Drugs*

5.1 *Tricyclic antidepressants*	*Reimbursed* †	*Cost Index* ‡	*Copay Tier/Amount* §
Amitriptline‖	Generic	$	Tier I $5
Imipramine	Generic	$	Tier I $5
Desipramine	Generic	$$	Tier I $5
Nortriptyline	Generic	$$	Tier I $5
5.2 Selective reuptake inhibitors (SRIs)			
Citalopgram (Celexa®)	Brand	$$$	Tier II $10
Paroxetine (Paxil®)	Brand	$$$$	Tier II $10
Sertraline (Zoloft®)	Brand	$$$$	Tier II $10
Note: only the 100-mg strength tablet of Zoloft is eligible for reimbursement.			
Fluoxetine (Prozac®)	Brand	$$$$$	Tier III $25
5.3 Other antidepressants			
Trazodone	Generic	$$	Tier I $5
Bupropion (Wellbutrin®)	Brand	$$$	Tier II $10

Source: Adapted from Michael J. Dillon, Drug Formulary Management, in *Managed Care Pharmacy Practice,* RP Navarro, ed, p 150, © 1999, Aspen Publishers, Inc. Copayment information added by Robert P. Navarro, 2000.

*Drugs listed by therapeutic category.

†Generic and brand indicator. This informs the prescriber that if the word "generic" is listed, the drug is subject to a maximum allowable cost (MAC) and only reimbursed at the generic level. If the brand name is included, the brand name drug is included on the formulary and reimbursed.

‡Relative cost index. Dollar signs ($) are used to indicate the relative cost of each covered drug within the same therapeutic class. This cannot be used to determine exact dollar cost of a prescription. The greater the number of dollar signs, the more costly the product.

§Copay tier and amount. This refers to the copayment tier in which the drug is positioned and the prescription copayment amount to be paid by the patient for each prescription. *Note:* The copayment amount is usually not listed, because it is subject to change and may be different for various payer groups. The copayment amount is included here to illustrate the cost difference among the various drugs on the basis of copayment tier.

‖Name of drug. The generic name of all drugs is included. The brand names are also listed for those drugs that are included as brand name drugs on the formulary and are reimbursed as brand drugs.

formulary. In this evaluative process, P & T committees review and consider the following factors, according to Dillon:[47]

- source of supply and reliability of manufacturer and distributor
- pharmacological considerations (e.g., drug class, similarity to existing drugs, adverse effect profile, mechanism of action, therapeutic indications, drug-drug interaction potential, clinical advantages over other products in drug class)
- unlabeled uses and their appropriateness
- bioavailability data
- pharmacokinetic data
- dosage ranges by route and age
- risk versus benefits regarding clinical efficacy and safety of a particular drug relative to other drugs with the same indication
- patient risk factors relative to contraindications, warnings, and precautions
- special monitoring or drug administration requirements
- pharmacoeconomic data
- cost comparisons against other drugs available to treat the same medical condition(s)[48]

P & T committees most commonly consider peer-reviewed clinical literature and information from the pharmaceutical manufacturer when evaluating a new drug. The P & T committee members, given the potential for bias, treat the manufacturer's findings with a slight degree of healthy skepticism. Information provided by the manufacturer is balanced by published research not sponsored by the drug's manufacturer, if possible. An ideal, yet uncommon, occurrence is identifying data from research conducted in a managed care practice in which the patient population matches that of the managed care organization that is reviewing the drug for possible formulary inclusion.

Role of Pharmacoeconomic Data in Evidence-Based Drug Formularies[49]

Pharmacoeconomics is a tool that can mitigate this continuing obsession with cost minimization and broaden the appreciation of payers to the economic and clinical value of pharmaceuticals and pharmacy programs. If this occurs, it would theoretically relieve some of the cost-containment pressure for pharmacy program managers and the pharmaceutical industry. However, payers (and as a result, managed care) will likely never be comfortable with rising costs, and the promise of pharmacoeconomics to allow a relaxation in strident pharmacy benefit controls is a partial delusion. It may likely have a positive impact but less so in the near term.

Pharmacy and medical directors, and P & T committees, have increased their requests for pharmacoeconomic (PE) data from the pharmaceutical industry. There is an intellectual appreciation of the need for such data to demonstrate how the appropriate use of cost-effective pharmaceuticals can contribute value broadly throughout the health care system. Economist Paul Langley suggests a "...systems-based approach...offers an analytic framework that...is likely to contribute significantly to the management of health care systems."[50] However, there is a fundamental challenge that may prevent the widespread dissemination and use of pharmacoeconomic data: many pharmacy and medical directors may not understand the concepts and may be uncertain as to how to implement pharmacoeconomic criteria within their P & T committee drug evaluation process. The Academy of Managed Care Pharmacy is publishing *Pharmacoeconomic Evaluations: Guidelines for Drug Purchasers* in an attempt to advance the understanding and application of pharmacoeconomic evaluation guidelines. Regence Health Plan is taking a proactive approach and requiring all manufacturers to submit a complete drug information dossier, complete with pharmacoeconomic data, before a drug is reviewed by the P & T committee.[51]

In a survey of 51 managed care organizations, Luce and colleagues found that clinical effectiveness remained more important than cost-effectiveness (second most important) or quality of life (third most important) in drug evaluations.[52] In general, there is a lack of understanding of the PE concepts and how to incorporate PE data into the drug formulary evaluation process. Cost minimization is widely accepted and used. Cost-effectiveness analysis (CEA) is generally understood, and if the data are credible and applicable, CEA data may be used. However, cost-benefit analysis, cost-utility metrics, and willingness to pay are concepts somewhat foreign and not widely used in the formulary process, even if the pharmaceutical manufacturer provides these data. There are exceptions, as seen with the comprehensive review and novel formulary treatment of salmeterol at the Dean Clinic.[53] Pharmaceutical manufacturers should continue to invest in PE research for most new drugs (except clearly undifferentiated products), but it must be designed to produce outcomes of interest to managed care.

Data suggest that research conducted in other HMOs or PBMs is used if it is credible and applicable. In early 1998, the Zitter Group conducted a national study of managed care decision makers entitled "Health Economics Leaders Study."[54] Results of the study reported that findings from health economics research conducted outside the managed care organizations were overwhelmingly used to make formu-

lary decisions if it was credible and applicable to managed care.

Acceptance of PE concepts, especially by payers, will help shift the focus from the cost of drugs to the value of drugs. As a result, this evolution will have a positive impact on improving access and use of cost-effective pharmaceuticals. It will be the responsibility of the manufacturer to have credible and applicable PE data to support the launch of novel pharmaceuticals. In the absence of such PE data that clearly demonstrate significant product differentiation, pharmacy and medical directors will assume products are similar (and thus interchangeable) and make formulary coverage decisions on cost rather than outcomes.

A controversy continues between the use of "efficacy" data and "effectiveness" data. Efficacy data are generated from randomized, controlled clinical trials of the genre submitted to the Food and Drug Administration (FDA) for the basis of new drug product approval. Effectiveness data are generated from "uncontrolled" studies often conducted in a managed care environment that reflects the naturalistic use and outcomes associated with the drug. Efficacy is a measure of the ideal performance of a drug product; effectiveness reflects how the drug is likely to perform in an uncontrolled environment. The FDA has required at least two pivotal efficacy studies to support new drug launches or new indications. However, by nature these efficacy studies are controlled and do not reflect how a drug will be used in a "real world" environment.

Therefore, managed care has requested that pharmaceutical manufacturers provide uncontrolled, real-world effectiveness research data and controlled efficacy trial data. Thus far, the FDA has restricted what effectiveness data manufacturers have been able to provide because the FDA seems to only consider controlled efficacy studies as valid. In late 1997, the U.S. Congress passed the FDA Modernization Act of 1997, which will influence the type and amount of PE data provided to P &.T committees from pharmaceutical manufacturers.[55] Section 114 of this act (Health Care Economic Information) amends the previous 1992 legislation by adding to Section 502(a) (21 U.S.C. 352(a)) the statement, "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee carrying out its responsibilities for the selection of drugs—shall not be considered to be false or misleading—if the information directly relates to an indication approved and is based on competent and reliable scientific evidence." The original intent of Section 114 was thought to allow manufacturers greater latitude in providing PE data from uncontrolled research to health plan decision makers and P & T committee members (not any or all participating provider physicians). The interpretation and practice of Section 114 remains controversial and unresolved. Thus far, pharmaceutical manufacturers have infrequently provided information under Section 114, and if it is not used, the right to do so may be rescinded by the FDA.

Paul Langley has the following opinion:[56]

> If our ultimate objective is to ensure that pharmaceutical manufacturers are not discouraged from producing pharmacoeconomic studies that meet the needs of drug purchasers in varied treating environments, then the FTC approach might appear the most appropriate. It still could involve an expert committee to review studies that are considered to be deceptive, but it would not be involved in policing initial proposals for pharmacoeconomic studies or reviewing those undertaken for promotion and marketing by pharmaceutical manufacturers.
>
> If the FDA takes the view that the phrase "competent and reliable scientific evidence" must be interpreted as evidence based on randomized-controlled experiments, then we are back to square one. If the FDA takes a more eclectic position and refers to accepted standards of professional practice within the appropriate discipline, in this case health care economics, then we can look forward to entering a more